

### REMARKS

Claim 16 has been amended. No new matter has been added. Thus, claims 1 - 23 remain pending in the above-referenced application.

Claims 1 - 8, 15 - 19 and 22 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over U.S. Patent No. 5,514,115 to Frantzen et al. ("Frantzen") or over International Published Application No. WO 02/36045 to Walak, hereinafter referred to as the '045 device. With respect to claim 1, the Examiner correctly concedes that neither of these references teaches the strain conditions or the stability of the martensitic phase, yet the Examiner claims he has made "a reasonable assumption that these parameters would also be the same or nearly so in the prior art and the claimed invention." (See 8/27/07 Office Action, p. 2). On the basis of this "reasonable assumption," the Examiner believes that a "prima facie case of obviousness is established." (*Id.*).

The Frantzen device is directed to a flexible elongated tubular housing for removing tissue or other material from a body lumen or cavity, such as an atherectomy catheter. (See Frantzen, col. 2, ll. 27 - 36; Fig. 4). In one embodiment, the Frantzen device is provided with "a plurality of heat treated cylindrically shaped tubular section 40 to provide improved housing flexibility." (See Frantzen, col. 7, ll. 3-6). In another embodiment, the housing of the Frantzen device is provided with "an elongated strip 50 in the martensite phase which is transformable to an austenite phase with a straight memory by the application of heat to raise the temperature of the strip to above the  $A_f$  temperature." (See Frantzen, col. 7, ll. 33- 38; Fig. 7). It is noted that, in both of the aforementioned embodiments, Frantzen discloses the placement of martensite portions of nitinol at marginal lengths of the housing, the placement following a pattern of even distribution throughout the length of the housing. (*Id.* at Figs. 4, 7).

However, Frantzen fails to teach or suggest the placement of the martensite portions at "high strain portions and lesser strain portion, wherein the high strain portions are to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions, the high strain portions comprising a material which is stabilized in a martensite phase when

deployed within the body and the lesser strain portions comprise a material which, under the predetermined operating conditions, is in a austenite phase", as recited in claim 1. Rather, Frantzen seeks to place martensite and austenite portions of the housing in an evenly distributed fashion, irrespective of portions that have greater or lesser strains.

It is respectfully submitted that the Examiner's assumptions about the cited reference are completely unsupported by the reference and that this assumption constitutes an improper hindsight reconstruction of the invention. For these reasons, it is respectfully submitted that a prima facie obviousness rejection is not allowable over Frantzen and that claim 1 and its dependent claims 2 - 8 and 15 are allowable.

Amended claim 16 recites limitations substantially similar to claim 1, including "a *super-elastic lesser strain core portion* of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and a *fatigue resistant high strain surface portion* primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized, *wherein, during use, the high strain portion is to be subjected to levels of strain increased with respect to strain levels in the lesser strain portion.*" It is therefore submitted that claim 16 and its dependent claims 17 - 19 and 22 are allowable over Frantzen for the same reasons noted above with regard to claim 1.

The '045 patent purports to describe an endoluminal device such as a stent comprising at least one superelastic section and at least one plastically deformable section. (See Walak, p. 3, ll. 1-2). Various embodiments of the '045 device include superelastic portions disposed at various longitudinal lengths of the device, the placement of the superelastic portions being designed to allow the device to "be tailored to conform to the anatomy of a lumen in which it is deployed by deforming the plastically deformable section of the device without changing the characteristics of the superelastic section of the device." (See *Id.*, p. 17, ll. 4-14; Figs. 1, 4A-4F, 7A-7F). It is therefore noted that the placement of the plastically deformable (martensite) portions along the '045 device is dictated to allow for an even distribution of flexibility along the

device and is in no way linked to the location of "high strain portions and lesser strain portion, wherein the high strain portions are to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions, the high strain portions comprising a material which is stabilized in a martensite phase when deployed within the body and the lesser strain portions comprise a material which, under the predetermined operating conditions, is in a austenite phase", as recited in claim 1. As with Frantzen, the '045 patent makes no mention of strain as a deciding factor in the placement of the superelastic portions and it is submitted that any suggestion that the locations of these plastically deformable portions is based on the location of high and lesser strain portions is unsupported by the '045 patent.

It is respectfully submitted that the Examiner's assumptions about the '045 patent are completely unsupported by the reference and that this assumption constitutes an improper hindsight reconstruction of the invention. For these reasons, it is respectfully submitted that a prima facie obviousness rejection is not allowable over the '045 patent and that claim 1 and its dependent claims 2 - 8 and 15 are allowable.

Amended claim 16 recites limitations substantially similar to claim 1, including "*a super-elastic lesser strain core portion of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and a fatigue resistant high strain surface portion primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized, wherein the high strain portion is to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portion.*" It is therefore submitted that claim 16 and its dependent claims 17 - 19 and 22 are allowable over the '045 patent for the same reasons noted above.

In a section entitled "Basic Requirements of a *Prima Facie* Case of Obviousness," the MPEP (Section 2143) states that the "prior art reference (or references when combined) must teach or suggest all the claim limitations." Accordingly, it is respectfully submitted that neither Frantzen nor the '045 patent "teach or suggest all the claim limitations," and a withdrawal of the rejection is respectfully requested.

Claims 1, 3 - 8, 14 - 19, 22 and 23 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over U. S. Patent No. 6,923,829 to Boyle et al. ("Boyle").

Boyle purports to describe endoluminal devices "having regions that are either plastically deformable or are sufficiently martensitic to behave pseudoplastically in vivo, and regions that are elastically deformable or sufficiently austenitic to behave pseudoelastically or superelastically in vivo." (See Boyle, col. 4, ll. 16-21). The only description in Boyle in regard to placement of the martensitic and austenitic portions, pertains to placements allowing for a maximization of plastic deformability. (See Boyle, col. 4, ll. 30-45). Boyle does not disclose or suggest the placement of martensitic portions based on strain to which the portions of the device will be subjected during use," as recited in claim 1. Accordingly, it is respectfully submitted that Boyle does not teach or suggest the limitations of claim 1 and that claim 1 and its dependent claims 3 - 8 and 14 - 15 are allowable.

Amended claim 16 recites limitations substantially similar to claim 1, including "a *super-elastic lesser strain core portion* of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and a *fatigue resistant high strain surface portion* primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized, *wherein the high strain portion is to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portion.*" It is therefore submitted that claim 16 and its dependent claims 17 - 19, 22 and 23 are allowable over Boyle for the same reasons noted above.

Claims 2, 9 - 13, 20, and 21 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over Boyle in view of U. S. Patent No. 5,964,770 to Flomenblit et al. ("Flomenblit").

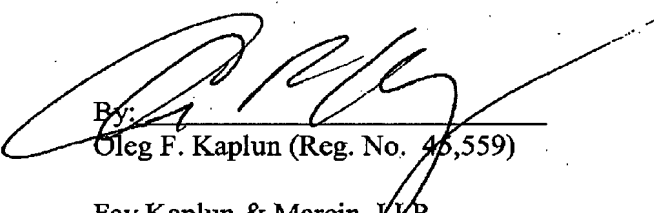
As noted above, Boyle does not teach the limitations of claim 1, including the placement of martensitic portion based on the strain to which portions of the device will be subjected during use," as recited in claim 1 or "a *super-elastic lesser strain core portion* of the element being

primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and *a fatigue resistant high strain surface portion* primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized, *wherein the high strain portion is to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portion.*" as recited in claim 16. Flomenblit does not cure this deficiency. It is respectfully submitted that claims 2, 9 - 13, 20, and 21 are allowable over Boyle and Flomenblit as being dependent on the allowable base claims 1 and 16, as noted above.

All issues raised by the Examiner having been addressed, Applicants submit that the application is in condition for allowance.

Respectfully submitted,

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